

## 1.9 Configure Institution AE Notification Triggers

### Description

This use case will capture configuration of AE notification triggers at the institution level. An entity within an institution (e.g IRB, DSMB) will dictate the triggers for notification on all protocols regardless of type. The triggers are invoked when an AE is created and stopped when all notifications are completed and/or the notification period has been passed (**\*SIG: verify if this is valid**).

### Actors

The System Administrator (SA) or any other designated user of *AERS*<sup>sm</sup> with appropriate SA role authority.

### Pre-Conditions

The actor has identified and assigned all personnel to appropriate roles and configured email addresses or email lists for notification. The actor has successfully logged into the system.

### Basic Course

1. The actor selects option to configure Sponsor Level Notification Triggers.

2. *AERS*<sup>sm</sup> presents a Trigger Builder. The actor configures the following AE notification trigger rules or turns them 'OFF' if not applicable.

- TRIGGER CATEGORY: selects from pre-filled list or input if not found
- TRIGGER TITLE: inputs trigger title in textfield
- AE CATEGORY: selects AE category from pre-filled list if interested in creating a trigger for a specific AE
- AE TERM: selects AE Term from pre-filled list if interested in creating a trigger for a specific AE
- PROTOCOL ID: selects 'OFF' or 'ALL' or one or more protocols from key word search or ID
- SPONSOR ID: selects 'OFF' or a sponsor from key word search or ID
- GRADE: Selects equality symbol and inputs targeted grade
  - >=, >, <, <=
  - 1,2,3,4 or 5
- HOSPITALIZATION: selects:
  - Hospitalized
  - Extended Hospitalization
  - No
- EXPECTEDNESS: selects 'OFF' or one below
  - Expected
  - Unexpected
- ATTRIBUTION: selects 'OFF' or one or more below
  - Unrelated
  - Unlikely Related
  - Possibly Related
  - Probably Related
  - Definitely Related

- PHASE: selects 'OFF' or one or more below
  - Pilot/Feasibility,
  - Phase I
  - Phase II
  - Phase III
  - Phase IV
- NOTIFICATION PERIOD: enter number of business days for total reporting period

3. The actor configures the notification, timing and escalation rules in the Trigger Builder:

- Configure reporting days for protocol staff notification
  - Select the day/hrs of reporting period (e.g. If 10 day reporting period, select day 1 if notification should occur on this day)
  - Select one or more protocol staff roles.
  - Select notification method (e.g. email, pager, application notification on login)
  - Complete notification message (e.g. Subject: "IRB Reportable AE", Text: "AE created on \*date and met IRB SAE reporting requirements. AE data needs completion for report generation")
  - Repeat for all interested days of reporting period, especially day just prior to reporting deadline and, optionally, x days after reporting deadline (e.g. to enter follow-up data)
- If application should notify on login of selected staff, check box "APPLICATION NOTIFICATION ON LOGIN"

4. The actor submits selection and confirms notification rule summary.

### **Post Conditions**

The SA has created an institution level notification trigger which includes trigger, protocol staff notification and escalation rules and entity to report to.

### **Alternate Course**

Pending

### **Use Case Dependency**

- 1.5 Create AE
- 1.6 AE Data Collection
- 1.8 Configure Protocol Staff for AE Notification
- 4.2 Create Report

**Data Item**

<b>Data Item</b>	<b>Type</b>	<b>Validation</b>
Trigger Category	Required	Pending
Trigger Title	Required	Pending
AE Category	Not Required	Pending
AE Term	Not Required	Pending
Protocol ID	Not Required	Pending
Sponsor ID	Not Required	Pending
Grade	Required	Pending
Hospitalization	Not Required	Pending
Expectedness	Not Required	Pending
Attribution	Not Required	Pending
Phase	Not Required	Pending
Notification Period	Required	Pending
Protocol Staff Roles	Required	Pending

**Notes**

None identified at this time.

**Risks**

Pending

**Use Case dependency**

13.0 User login

1.1 Create Protocol Data for AE Abstraction

1.2 Create and Link Study Participant to Protocol

1.5 Create AE Entry